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NOV - 2 2000

K002456

BD

Indispensable to human health

I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary Of Safety and Effectiveness

I. General Information

This Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA of 1990 and 21 § 807.92

Establishment:

- Address: Becton Dickinson VACUTAINER System
  1 Becton Drive
  Franklin Lakes, NJ 07417-1885
- Registration Number: 2243072
- Contact Person: James Haynes
  Regulatory Affairs Specialist
  Telephone no.: 201-847-5170
  Fax No. 201-847-4858
- Date of Summary: October 30, 2000

Device

- Trade Name: MICROTAINER™ Brand Sodium Fluoride/EDTA Tubes with MICROGARD™ Closure
- Classification Name: Tubes, Vials, Systems, Serum Separators, Blood Collection
- Classification: Class II
- Performance Standards: None Established under 514 of the Food, Drug and Cosmetic Act

II. Safety and Effectiveness Information Supporting Substantial Equivalence

Substantial Equivalence Declaration:

The term "Substantial Equivalence" as used in this 510(k) Premarket Notification is limited to the definition of Substantial Equivalence found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR § 807, Subpart E, under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of, substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

- Device Description

The MICROTAINER™ Brand Chemistry Tubes with MICROGARD™ Closure are non-sterile, single use microcollection tubes. The tubes consist of a wide diameter polypropylene reservoir with an integral blood collector component, and a skirted polyethylene closure with a recessed plug that reduces user exposure to blood. The Sodium Fluoride/EDTA additive functions as an anticoagulant and to inhibit glycolysis for 24 hours after collection.

- Intended Use

The MICROTAINER™ Brand Chemistry Tubes with MICROGARD™ Closure are designed to collect, transport, and store skin puncture blood specimens for chemistry testing requiring serum or plasma. The MICROTAINER™ Brand Sodium Fluoride/EDTA Tube is used for glucose determinations.

- Synopsis of Performance Study Results

Clinical testing was done to compare the performance of the predicate MICROTAINER™ Brand SST Tube, with the principal device, the MICROTAINER™ Brand Sodium Fluoride/EDTA Tube with MICROGARD™ Closure.

The first part of these studies evaluated the tubes for hemolysis and clotting. The studies concluded that the principal device, the MICROTAINER™ Brand Sodium Fluoride/EDTA Tube with MICROGARD™ Closure (evaluation tube), demonstrated clinically equivalent performance compared to the predicate device, the MICROTAINER™ Brand SST Tube (control tube). The studies showed no clotting in any of the evaluation tubes, and acceptable levels of trace hemolysis in the both the control tubes and the evaluation tubes.

The second part of these studies compared the performance of the evaluation tube to a control tube using the Johnson & Johnson Vitros 250 Chemistry Analyzer to measure glucose. Results from these studies concluded that the principal device, the MICROTAINER™ Brand Sodium Fluoride/EDTA Tube, demonstrated clinically

equivalent results to the predicate device, the MICROTAINER™ Brand SST Tube for glucose determinations. There was a statistical negative bias, however, it was concluded to be clinically insignificant. The final reports can be referenced in Attachment 1 of the submission.

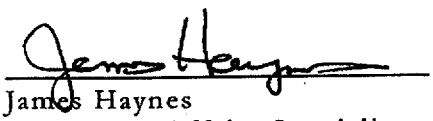
In conclusion, the data supports a determination of equivalent performance between the MICROTAINER™ Brand Sodium Fluoride/EDTA Tube with MICROGARD™ Closure as presented in this submission and the currently marketed predicate devices.

III. Predicate Device Summary Table

- Substantial Equivalence

Based on comparison of the intended use and principles of operation in the first case, and design, technology / principles of operation and materials in the second, the MICROTAINER™ Brand Sodium Fluoride/EDTA Tubes with MICROGARD™ Closure have been shown to be substantially equivalent to the commercially available predicate devices indicated in the table below. The predicate devices, K number, and clearance dates are also identified in the table.

Manufacturer	Predicate Device	K-Number	Clearance Date
Becton Dickinson VACUTAINER Systems	MICROTAINER™ Brand SST Tubes	K771370	8/3/77
Becton Dickinson VACUTAINER Systems	MICROTAINER™ Brand EDTA Tubes with MICROGARD™ Closure	K931368/A	9/28/93
Becton Dickinson VACUTAINER Systems	MICROTAINER™ Brand Tubes with MICROGARD™ Closure	K991702	7/28/99



October 30, 2000

James Haynes
Regulatory Affairs Specialist
Becton Dickinson VACUTAINER Systems
Becton Dickinson and Company

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 2 2000

Mr. James Haynes
Regulatory Affairs Specialist
BD Preanalytical Solutions
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K002456
Trade Name: MICROTAINER™ Brand Sodium Fluoride/EDTA tube with MICROGARD™ Closure
Regulatory Class: II
Product Code: JKA
Dated: October 12, 2000
Received: October 13, 2000

Dear Mr. Haynes:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

B. INDICATIONS FOR USE

510(k) Number (if known): K002456

Device Name: MICROTAINER™ Brand Sodium Fluoride/EDTA tube with MICROGARD™ Closure

Indications for Use:

The MICROTAINER™ Brand Chemistry tubes with MICROGARD™ Closure are intended to collect, transport, and store skin puncture blood specimens for chemistry determinations requiring serum or plasma. The MICROTAINER™ Brand Sodium Fluoride/EDTA Tube with MICROGARD™ Closure is used for glucose determinations.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002456

(Please do not Write below this line-continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-the-Counter Use _____

(Per 21 CFR § 801.109)

(Optional format 1-2-96)